# UNITED STATES PATENT AND TRADEMARK OFFICE

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| 10/749,101 | 12/30/2003 | James P. Martucci | EIS-5909B (1417G P 978) | 3167 |

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| EXAMINER |
|---|
| ALTSCHUL, AMBER L |

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

elizabeth_eich@baxter.com

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE <u>3</u> MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.
- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on <u>30 December 2003</u>.

2a)☐ This action is **FINAL**.   2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) <u>1-35</u> is/are pending in the application.

    4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) <u>1-35</u> is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

    Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

    Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

    a)☐ All   b)☐ Some * c)☐ None of:

      1.☐ Certified copies of the priority documents have been received.

      2.☐ Certified copies of the priority documents have been received in Application No. _____.

      3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

    * See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1)☒ Notice of References Cited (PTO-892)
2)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3)☒ Information Disclosure Statement(s) (PTO/SB/08)
    Paper No(s)/Mail Date <u>August 6, 2004, July 6, 2005, June 23, 2006</u>.

4)☐ Interview Summary (PTO-413)
    Paper No(s)/Mail Date. _____ .
5)☐ Notice of Informal Patent Application
6)☐ Other: _____ .

## DETAILED ACTION

1.    Claims 1-35 have been presented for examination.

### *Priority*

2.    This application claims benefit of a United States Provisional Application Number 60/443,350 filed February 1, 2003, United States Patent Application 10/135,180 filed on April 30, 2002, United States Patent Application 10/424,553 filed April 28, 2003 and United States Patent Application 10/659,760 filed September 10, 2003.    Applicant's claim for the benefit of these prior-filed applications is acknowledged.

### *Information Disclosure Statement*

3.    The examiner has reviewed the patents and articles supplied in the Information Disclosure Statements (IDS) provided on August 6, 2004, July 6, 2005 and June 23, 2006.

### *Claim Rejections - 35 USC § 102*

4.    The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4.      Claims 1-35 are rejected under 35 U.S.C. 102(e) as being unpatentable over United States Patent Number 6,408,330, DeLaHuerga, et al., hereinafter DeLaHuerga.

5.      As per claim 1, DeLaHuerga teaches a method for verifying medical device settings within a healthcare system comprising the steps of:

transmitting data relating to operational parameters from the medical device to a first computer, (column 2, lines 48-55),

storing data relating to an order in a memory of the first computer, (column 3, lines 16-21), and,

comparing at least one of the operational parameters sent from the medical device to at least a portion of the order, (column 36, lines 65-67 and column 37, lines 1-16).

6.      As per claim 2, DeLaHuerga teaches the method of claim 1 as described above. DeLaHuerga further teaches further comprising the step of transmitting a comparison result signal, (column 37, lines 17-42).

7.      As per claim 3, DeLaHuerga teaches the method of claims 1-2 as described above. DeLaHuerga further teaches further comprising the step of transmitting the comparison result signal from the first computer to a remote computer, (column 37, lines 17-31).

8.      As per claim 4, DeLaHuerga teaches the method of claims 1-3 as described above. DeLaHuerga further teaches wherein the remote computer is a wireless handheld device, and further comprising the step of transmitting a wireless comparison result signal to the wireless handheld device, (column 5, lines 41-54).

9.      As per claim 5, DeLaHuerga teaches the method of claim 1 as described above. DeLaHuerga further teaches wherein the transmission of operational parameters is secure, (column 43, lines 19-28).

10.     As per claim 6, this claim is rejected for the same reasons as set forth in claim 5 above.

11.     As per claim 7, DeLaHuerga teaches the method of claim 1 as described above. DeLaHuerga further teaches , further comprising the step of providing for transmitting the order data from a second computer to the first computer, (column 1, lines 18-27).

12.     As per claim 8, DeLaHuerga teaches the method of claims 1 and 7 as described above. DeLaHuerga further teaches wherein the transmission of the order data from the second computer to a first computer is via a secure communication line, (column 1, lines 18-27).

13.     As per claim 9, DeLaHuerga teaches the method of claim 1 as described above. DeLaHuerga further teaches wherein the data relating to the order comprises data for a patient identifier and a prescription identifier, (column 1, lines 36-47 and column 9, lines 42-49).

14.     As per claim 10, DeLaHuerga teaches the method of claim 1 as described above. DeLaHuerga further teaches wherein the operational parameters comprise settings manually programmed into the medical device, (column 9, lines 55-64).

15.     As per claim 11, DeLaHuerga teaches the method of claim 1 as described above. DeLaHuerga further teaches operational parameters are downloaded into the medical device from the first computer, (column 43, lines 19-28).

16.     As per claim 12, DeLaHuerga teaches the method of claim 1 as described above. DeLaHuerga further teaches wherein the operational parameters are downloaded into the medical device from a remote computer, (column 1, lines 18-27).

17.     As per claim 13, DeLaHuerga teaches the method of claim 1 as described above. DeLaHuerga further teaches comprising the step of comparing a primary/piggyback operational parameter, (column 37, lines 17-31 and column 43, lines 19-28).

18.     As per claim 14, DeLaHuerga teaches the method of claim 1 as described above. DeLaHuerga further teaches wherein the medical device is a pump controller, (column 17, lines 38-54).

19.     As per claim 15, DeLaHuerga teaches the method of claims 1 and 14 as described above. DeLaHuerga further teaches wherein the pump controller controls an in-line MEMS device, (column 17, lines 38-54).

20.     As per claim 16, this claim is rejected for the same reasons as claims 1-4 above.

21.      As per claim 17, DeLaHuerga teaches the method of claim 16 as described above. DeLaHuerga further teaches wherein the data relating to settings comprises at least a programmed infusion rate, wherein the data relating to the order comprises at least a prescribed infusion rate, and wherein the step of comparing data comprises the step of comparing the programmed infusion rate to the prescribed infusion rate, (column 17, lines 37-55 and column 58, lines 1-16).

22.      As per claim 18, DeLaHuerga teaches the method of claim 16 as described above. DeLaHuerga further teaches wherein the data relating to settings comprises at least a

programmed infusion dose, wherein the data relating to the order comprises at least a prescribed

infusion dose, and wherein the step of comparing data comprises the step of comparing the

programmed infusion dose to the prescribed infusion dose, (column 17, lines 37-55 and column

58, lines 1-16).

23.     As per claim 19, DeLaHuerga teaches the method of claim 16 as described above.

DeLaHuerga further teaches wherein wherein the data relating to settings comprises at least a

programmed infusion volume, wherein the data relating to the order comprises at least a

prescribed infusion volume, and wherein the step of comparing data comprises the step of

comparing the programmed infusion volume to the prescribed infusion volume, (column 17,

lines 37-55 and column 58, lines 1-16).

24.     As per claim 20, DeLaHuerga teaches the method of claim 16 as described above.

DeLaHuerga further teaches comprising the step of linking a patient identifier and an order

identifier, (column 1, lines 36-47 and column 9, lines 42-49).

25.     As per claim 21, DeLaHuerga teaches the method of claims 16 and 20 as described

above.  DeLaHuerga further teaches further comprising the step of linking a pumping channel

with the patient identifier and the order identifier, (column 1, lines 36-47 and column 9, lines 42-

49).

26.     As per claim 22, DeLaHuerga teaches the method of claims 16 and 20 as described

above.  DeLaHuerga further teaches comprising the steps of precluding a comparison of the data

transmitted from the medical device to the data in the order where a link between the patient

identifier and the order identifier is not established, (column 1, lines 36-47 and column 9, lines 42-49).

27.     As per claim 23, DeLaHuerga teaches the method of claim 16 as described above. DeLaHuerga further teaches comprising the step of checking if the data transmitted to the first computer relating to settings from the medical device is fresh data, (column 9, lines 55-64).

28.     As per claim 24, DeLaHuerga teaches the method of claims 16 and 23 as described above.  DeLaHuerga further teaches further comprising the step of requesting new data if the data transmitted to the first computer relating to settings from the medical device is not fresh data, (column 43, lines 19-28).

29.     As per claim 25, DeLaHuerga teaches the method of claim 16 as described above. DeLaHuerga further teaches further comprising the step of accepting a mismatched comparison result, (column 37, lines 17-31 and column 43, lines 19-28).

30.     As per claim 26, DeLaHuerga teaches the method of claims 16 and 25 as described above.  DeLaHuerga further teaches further comprising the step of recording an administration result, (column 1, lines 36-47).

31.     As per claims 27 is rejected for the same reasons as claim 26 above.

32.     As per claim 28, this claim is rejected for the same reasons as set forth in claims 1-4 and 16 above.

33.     As per claim 29, DeLaHuerga teaches the method of claim 16 as described above. DeLaHuerga further teaches further comprising the step of transmitting a cannot compare signal if channel data is erroneous, (column 4, lines 15-22).

34.    As per claim 30, this claim is rejected for the same reasons as set forth in claims 1-4, claims 7-8 and 13 above.

35.    As per claim 31, DeLaHuerga teaches the system of claim 30 as described above. DeLaHuerga further teaches a further comprising a wireless transmitter electrically connected to the medical device to send a wireless signal containing the data relating to the medical device's operational parameters to the first computer, (column 5, lines 41-54).

36.    As per claim 32, DeLaHuerga teaches the system of claim 30 as described above. DeLaHuerga further teaches a further comprising a second computer that sends the data relating to the medication order to the first computer, (column 1, lines 18-27).

37.    As per claim 33, DeLaHuerga teaches the system of claim 30 as described above. DeLaHuerga further teaches a wherein the remote computer is a wireless handheld device, (column 5, lines 41-54).

38.    As per claim 34, DeLaHuerga teaches the system of claim 30 as described above. DeLaHuerga further teaches a further comprising a second computer that sends patient information data to the first computer, (column 1, lines 18-27).

39.    As per claim 35, DeLaHuerga teaches the system of claims 30 and 34 as described above. DeLaHuerga further teaches a wherein the patient information comprises at least one of patient identification, room assignment, bed assignment, and admission status, (column 9, lines 41-49).

### *Conclusion*

40.     The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.


41.     Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amber L. Altschul whose telephone number is (571) 270-1362. The examiner can normally be reached on M-Th 7:30-5, F 7:30-4, every other Friday Off.


42.     If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gerald J. O'Connor can be reached on (571) 272-6787.  The fax phone numbers for the organization where this application or proceeding is assigned are (571) 273-8300.


43.     Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-8219.


44.     Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) method. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR method, see http://pair-direct.uspto.gov.  Should you have questions on access to the Private PAIR method, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).  If you

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would like assistance from a USPTO Customer Service Representative or access to the

automated information method, call 800-786-9199 (IN USA OR CANADA) or (571) 272-1000.

/A. L. A./
Examiner, Art Unit 3686
March 14, 2009

/Gerald J. O'Connor/
Supervisory Patent Examiner
Group Art Unit 3686